DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2014

Biolase Incorporated
Ms. Colleen Boswell
Vice President, Regulatory Affairs/Quality Assurance
4 Cromwell
Irvine, California 92618

Re: K140120
Trade/Device Name: Epic 10
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 15, 2014
Received: September 16, 2014

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.10 13:24:59 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *Epic 10*

Indications for Use:
The *Epic 10* is intended for use as a laser surgical instrument requiring the incision, excision, vaporization, ablation and hemostasis, or coagulation of soft tissue. It is indicated for the following expanded Indications for Use:

General Surgery, Dermatology, Plastic Surgery and Podiatry

- Debridement of wounds

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

BIOLASE® | BIOLASE, Inc.
4 Cromwell
Irvine, CA 92618

510(k) Summary

Submitter:

Biolase, Inc.
4 Cromwell
Irvine, California 92618
(949) 226-8470 - Phone
(949) 273-6688 - Facsimile
Colleen Boswell - Contact Person
Date Summary Prepared: October 2014

- Trade Name - *Epic 10*
- Common Name - Diode Laser
- Classification Name - Laser surgical instrument for use in general and plastic surgery and in dermatology, per 21 CFR 878.4810
- Product Code - GEX

Devices for Which Substantial Equivalence is Claimed:

- *QUANTA Diode Laser Family,* Quanta System, S.p.A., K100558
- *Ceralas D980 Diode Laser (Models D15, D25),* Biolitec, Inc., K072779
- *Vectra Laser System and Accessories,* Xintec Corporation, dba, Convergent Laser Technologies, K060114

Device Description

The *EPIC 10* system uses an Indium Gallium Arsenide Phosphorous (InGaAsP) solid state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a handpiece that emits the energy to the target site. A visible light is emitted at the same time to visually identify the treatment location. The *EPIC 10* laser is comprised of a base console, a detachable delivery system, tips, and a wireless footswitch. Various types of the single use tips are included for different applications and the device is activated by means of a wireless footswitch. The *Epic 10* delivery system consists of the following: Fiber Optic Assembly, Surgical Handpiece, and Single-use tips.

Statement of Intended Use

The *Epic 10* is intended for use as a laser surgical instrument requiring the incision, excision, vaporization, ablation, and hemostasis, or coagulation of soft tissue. It is indicated for the following expanded Indications for Use:

General Surgery, Dermatology, Plastic Surgery and Podiatry

- Debridement of wounds

Summary of Technological Characteristics

Descriptive Information	***Epic 10 (K140120)***	**QUANTA Diode Laser Family (K100558)**	**Ceralas Diode 980nm Laser System (Models D15, D25) (K072779)**	**Vectra Laser System and Accessories (K060114)**
Company	**Biolase, Inc.**	Quanta System S.p.A.	Biolitec, Inc.	Xintec Corporation, dba, Convergent Laser Technologies
Indications for Use	The *Epic 10* is intended for use as a laser surgical instrument requiring the incision, excision, vaporization, ablation and hemostasis, or coagulation of soft tissue. **It is indicated for the following expanded Indications for Use:** ***General Surgery, Dermatology, Plastic Surgery and Podiatry*** • Debridement of wounds	***General Surgery, Dermatology, Plastic Surgery and Podiatry*** Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include: • Matrixectomy • Excision of neuromas • Excision of periungual and subungual warts • Excision of plantar warts • Excision of keloids • Liver resection • Excision of cutaneous lesions • Hemorrhoidectomy • Appendectomy • Debridement of decubitus ulcers • *Hepatobiliary tumors* • Mastectomy	***General Surgery, Dermatology, Plastic Surgery and Podiatry*** Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include: • Matrixectomy • Excision of neuromas • Excision of periungual and subungual warts • Excision of plantar warts • Excision of keloids • Liver resection • Excision of cutaneous lesions • Hemorrhoidectomy • Appendectomy • Debridement of decubitus ulcers • *Hepatobiliary tumors* • Mastectomy	***General Surgery, Dermatology, Plastic Surgery and Podiatry*** Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include: • Matrixectomy • Excision of neuromas • Excision of periungual and subungual warts • Excision of plantar warts • Excision of keloids • Liver resection • Excision of cutaneous lesions • Hemorrhoidectomy • Appendectomy • Debridement of decubitus ulcers • *Hepatobiliary tumors* • Mastectomy

Descriptive Information	*Epic 10 (K140120)*	QUANTA Diode Laser Family (K100558)	Ceralas Diode 980nm Laser System (Models D15, D25) (K072779)	Vectra Laser System and Accessories (K060114)
		• Dermabrasion • Vaporization and hemostasis of capillary hemangioma • Excision, vaporization and hemostasis of abdominal tumors • Excisions, vaporization and hemostasis of rectal pathology • Pilonidal cystectomy • Herniorapphy • Adhesiolysis • Parathyroidectomy • Laparoscopic cholecystectomy • Thyroidectomy • Resection of organs • Debridement of wounds • Photocoagulation of teleangectasis of the legs and face • Photocoagulation of vascular lesions of the face and extremities • Endovascular coagulation of the greater saphenous vein of the thigh in patients with *superficial vein reflux* • Treatment of reticular veins	• Dermabrasion • Vaporization and hemostasis of capillary hemangioma • Excision, vaporization and hemostasis of abdominal tumors • Excisions, vaporization and hemostasis of rectal pathology • Pilonidal cystectomy • Herniorapphy • Adhesiolysis • Parathyroidectomy • Laparoscopic cholecystectomy • Thyroidectomy • Resection of organs • Debridement of wounds • Photocoagulation of teleangectasis of the legs and face • Photocoagulation of vascular lesions of the face and extremities	• Dermabrasion • Vaporization and hemostasis of capillary hemangioma • Excision, vaporization and hemostasis of abdominal tumors • Excisions, vaporization and hemostasis of rectal pathology • Pilonidal cystectomy • Herniorapphy • Adhesiolysis • Parathyroidectomy • Laparoscopic cholecystectomy • Thyroidectomy • Resection of organs • Debridement of wounds • Photocoagulation of teleangectasis of the legs and face • Photocoagulation of vascular lesions of the face and extremities • Endovascular coagulation of the greater saphenous vein of the thigh in patients with *superficial vein reflux* • Treatment of reticular veins

Descriptive Information	*Epic 10 (K140120)*	**QUANTA Diode Laser Family (K100558)**	**Ceralas Diode 980nm Laser System (Models D15, D25) (K072779)**	**Vectra Laser System and Accessories (K060114)**
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Laser Classification	IV (4)	IV (4)	IV (4)	IV (4)
Operating Voltage	100 - 240V ~ 1.5A	100 - 240V	100 - 220V	100 - 220 VAC
Laser Medium	InGaAsP	Diode Laser	GaAlAs	Diode Laser
Wavelength	940 ± 10nm	980nm	980nm	980nm ± 10% (882 – 1078 nm)
Current Frequency	50 - 60 Hz	50 - 60 Hz	50 - 60 Hz	50 – 60 Hz
Max Output Power	10 W	30W	15W (D15), 25W (D25)	10/20/30W; 60W; 80W; 100W; 120W
Power Mode	Continuous, Pulse Modulation	**Continuous, Pulse Modulation**	**Continuous, Pulse Modulation**	**Continuous, Pulse Modulation**
Pulse Repetition Rate	Up to 20 KHz	1 - 200 Hz	Not Listed by Manufacturer	Not Listed by Manufacturer
Pulse Duration	0.01 ms - 30 ms	3 - 2500 ms	0.01 - 99.9 sec	Not Listed by Manufacturer
Aiming Beam	Laser Diode, max 1mW, 625 - 670nm, Class 3B	Laser Diode, max 3mW, 635, Class 3R	Laser Diode, max 4mW, 635	Laser Diode, Green, 532
Materials	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components

Non-Clinical Test Data

Non-clinical testing was not performed on this device since the purpose of this 510(k) is to only expand the Indications for Use from the previous 510(k) clearance under 510(k) No. K130465. The indication included in this 510(k) has already been cleared by the FDA for equivalent medical devices manufactured by Quanta System, S.p.A., Biolitec Inc. and Xintec Corporation, dba, Convergent Laser Technologies.

Clinical Test Data

Clinical testing was not conducted on this device.

Conclusion

Based upon the comparison of the *Epic 10* with the predicate devices previously cleared by the FDA, the clinical performance of the *Epic 10* for the Indication for Use described above is deemed to be substantially equivalent to the legally-marketed predicate devices, the QUANTA Diode Laser Family, the Ceralas Diode 980nm Diode Laser (Models D15, D25) and the Vectra Laser System and Accessories.